

REMARKS

The Office Action and the cited and applied references have been carefully reviewed. No claim is allowed. Claims 1-20, 23, 24, and 26-30 presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

The examiner states that the argument for traversal of the lack of unity requirement was fully considered but was found to be unpersuasive because the examiner holds that the cited Inbal et al. reference (SP TREMBL Database, Accession No. 075892, November 1998) is anticipatory to the polypeptide of Group I.

The sequence presented in the TrEMBL database, Accession No. 075892 was made available in November 1998 by the present inventor Adi Kimchi. A copy of a printout from TrEMBL for Accession No. 075892 shows that the sequence was provided by A. Kimchi, a co-author of the Inbal et al. Mol. Cell. Biol. 20:1044-1054 (2000), reference cited for the 075892 sequence.

The present application claims the benefit of U.S. provisional application no. 60/089,294, filed June 15, 1998. Accordingly, the TrEMBL Accession No. 075892 sequence, first made publicly available in November 1998, cannot anticipate

the present invention because it is not available as prior art. The June 15, 1998, filing date of U.S. provisional application no. 60/089,294 antedates the November 1998 date on which Accession No. 075892 was made available on the TrEMBL database. Moreover, as this sequence is the submission of the present inventor and the November 1998 "publication" date is within one year prior to the filing of the PCT application from which the instant application is a 371 national stage application, the cited sequence of Accession No. 075892 is also not available as a reference under 35 U.S.C. §102(a) or (b) insofar as the PCT International filing date of June 15, 1999, is concerned.

Reconsideration and withdrawal of the restriction requirement to the extent requested in the amendment filed May 6, 2002, is respectfully requested.

Claims 1 and 20 have been objected to because the term "property being" is confusing. Appropriate correction as suggested by the examiner is made to claim 1, thereby obviating this objection.

Claims 8, 13, 27 and 28 have been rejected under 35 U.S.C. §112, first paragraph, because the examiner states that the specification, while being enabling for polypeptides consisting of amino acid residues 13-275 of SEQ ID NO:2 or consisting of amino residues 321-360 of SEQ ID NO:2, does not

reasonably provide enablement for polypeptides comprising an amino acid sequence having 85% sequence identity to residues 13-275 or residues 321-360 of SEQ ID NO:2, wherein said polypeptides have no specific function. This rejection is respectfully traversed.

Claims 8 and 13 are now amended to recite that the polypeptide consisting of an amino acid sequence having at least 85% sequence identity to residues 13-275 of SEQ ID NO:2 or to residues 321-360 of SEQ ID NO:2 has the specific function of inducing cell death or inhibiting the induction of cell death, respectively. The amendments to claims 8 and 13 are supported in the specification at page 10, second paragraph. The specific function of the polypeptide as now recited in claims 8 and 13 along with the use of the closed "consisting of" language overcomes this enablement rejection.

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

Claims 1, 20 and 27 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The examiner indicates that the polypeptide of claims 1(E) and 1(F) are confusing because even though the polypeptide as claimed must lack the cell death domain, they must inhibit kinase activity which is disclosed to be only due to the action of the cell-death domain. The examiner finds it

unclear how the claimed polypeptides can simultaneously retain both functions recited. This rejection is respectfully traversed.

The specification at page 10, second paragraph, clarifies this issue. The fragment of claim 1(E) for instance comprises residues 13-275 of SEQ ID NO:2 and is capable of inducing cell death (i.e., super-killing) whereas the fragment of claim 1(F) comprises residues 321-360 of SEQ ID NO:2 and is capable of inhibiting the induction of cell death by the polypeptide of SEQ ID NO:2. The fragments of claim 1(E) and 1(F) as recited are not required to either have or lack kinase activity.

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

Claims 1, 8, 20, and 27 have been rejected under 35 U.S.C. §102(b) as being anticipated by Deiss et al. or Akira et al. The examiner holds that Deiss teaches a DAP kinase which has 83.7% identity to residues 13-275 of SEQ ID NO:2 and that Akira teaches a murine Zip kinase which has 82.4% identity to residues 13-275 of SEQ ID NO:2. The examiner asserts that sequence alignment results change upon changing analysis parameters and that 83.7% and 82.4% are very close to 85%. These two rejections are respectfully traversed.

Even if the 83.7% "query match" of Deiss with residues 130275 of SEQ ID NO:2 and the 82.4% "query match" of Akira are interpreted as "sequence identity", they simply do not anticipate the required feature of "at least 85% sequence identity" as recited in the rejected claims. Being close enough but still outside the percentage range recited does not anticipate. Furthermore, the "query match" indicated in the sequence alignments cited by the examiner is not equivalent to "sequence identity". As shown in the sequence alignments, a 263 residue query sequence is aligned with a 263 residue sequence of residues 13-275 of SEQ ID NO:2. There are no gaps in the aligned sequences of exactly the same length. Consequently, the percent sequence identity is unambiguously the number of exact matches (209 residues) divided by the total number of residue positions aligned (263 residues) and then multiplied by 100% to give for both Deiss and Akira: $\frac{209}{263} \times 100\% = 79.5\%$ sequence identity

Accordingly, Deiss or Akira cannot anticipate the presently claimed invention.

Reconsideration and withdrawal of the rejections are therefore respectfully requested.

Claims 1 and 8 have been rejected under 35 U.S.C. §102(a) as being anticipated by Inbal et al. As discussed

above, Inbal is not available as prior art because it was only made publicly available after the filing date of the U.S. provisional application on which the benefit of priority is claimed. Moreover, the sequence submission was made by the present inventor and is the present inventor's own invention. Therefore, for this reason also, Inbal et al. cannot be available as prior art under §102(a).

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

Claim 13 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Inbal in view of Kimchi and further in view of Kawai et al. This rejection is respectfully traversed.

As discussed above, Inbal is not available as prior art against the present claims and the applied secondary references Kimchi and Kawai et al. cannot make obvious the presently claimed invention. Accordingly, this rejection must fall.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

New claims 31-36 are fully supported in the specification at page 10, lines 24-28.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting

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their allowance. Favorable consideration and early allowance
are earnestly urged.

Respectfully submitted,

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VERSION WITH MARKING TO SHOW CHANGES MADE

Claims 1, 8 and 13 have been amended as follows:

1 (Amended). An isolated polypeptide, which is a calmodulin-dependent serine/threonine kinase, or a fragment thereof, selected from the group consisting of:

(A) a polypeptide which is capable of inducing cell death (apoptosis) and comprises the amino acid sequence of SEQ ID NO:2;

(B) a polypeptide which has a property of being capable of inducing cell death and has at least 85% sequence identity to the amino acid sequence of SEQ ID NO:2;

(C) a fragment of a polypeptide of SEQ ID NO:2 which is capable of inducing cell death;

(D) a fragment which is capable of inducing cell death and has at least 85% sequence identity to fragment (C);

(E) a fragment of a polypeptide of SEQ ID NO:2 which lacks the property of being capable of inducing cell death and which inhibits the ability of the polypeptide (A) or (B) to induce cell death; and

(F) a fragment which lacks the property of being capable of inducing cell death and which inhibits the ability of the polypeptide (A) or (B) to induce cell death, said fragment having at least 85% sequence identity to fragment (E).

8(Amended). A polypeptide capable of inducing cell death, consisting of an amino acid sequence selected from the group consisting of amino acid residues 13 to 275 of SEQ ID NO:2 and an amino acid sequence having at least 85% sequence identity to residues 13 to 275 of SEQ ID NO:2.

13(Amended). A polypeptide capable of inhibiting the ability of the polypeptide of SEQ ID NO:2 to induce cell death, consisting of an amino acid sequence selected from the group consisting of amino acid residues 321 to 360 of SEQ ID NO:2 and an amino acid sequence having at least 85% sequence identity to residues 321 to 360 of SEQ ID NO:2.